

ISMS QMS Integration

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Bio

- Tom is the Assurance Manager for the DOE SRS Salt Waste Processing Facility Project, and has also served as the ISMS & Assessment Manager, and Environmental Manager
- Tom received his M.S. and Ph.D. at UT a couple of decades ago and has worked in the DOE environmental restoration/waste management arena since

Introduction

- **Integration:** To bring differing elements or parts together as one.
- **Management System:** An organization's documented set of policies, plans, procedures, programs devised and implemented to obtain mission objectives
- **Problem Statement:** How and what does the contractor need to do, if anything, to affect direction to integrate ISMS and QMS?

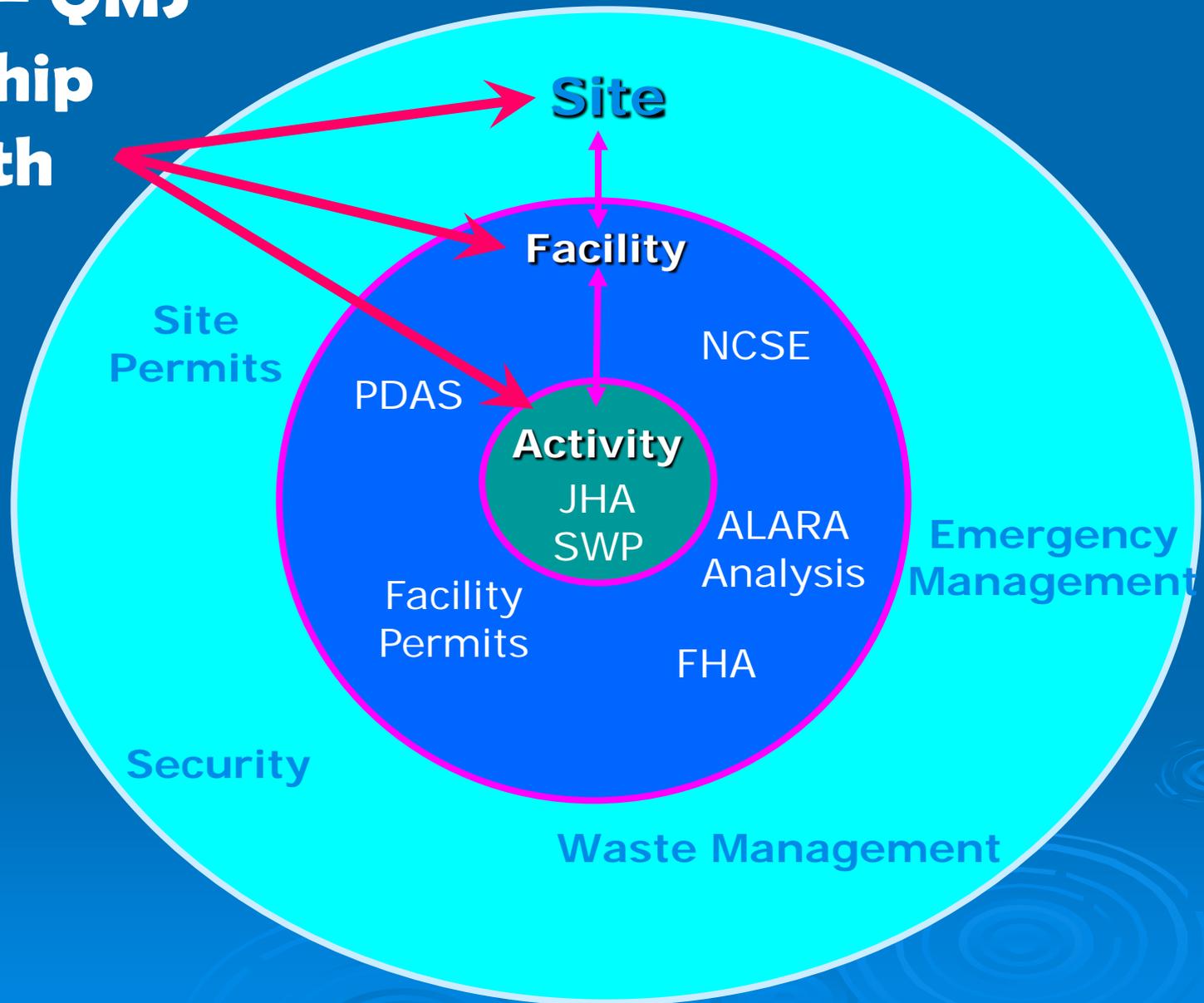
Requirements

- DOE O 414.1C: The Quality Assurance Program (QAP) “Integrates, where practicable and consistent ... with other ... management system requirements ... including ... DOE P 450.4, *Safety Management System Policy*.”

Bring Together QMS & ISMS?

- Obvious points of overlap: Corrective Action, Management Assessment, Training and Qualifications. . . HOWEVER:
 - QA/QC is concerned with Items and Services
 - ISMS is about Protecting the Environment, the Worker and the Public

The ISMS – QMS Relationship Varies with Scope



Where they Diverge

- QA and ISM diverge at the Activity Level
- Activity-level ISMS finds little commonality with QA elements such procurement document control, item receipt inspection, design control, etc.
- The controls delineated in NQA-1 find scant utility in the development of a JHA or a pre-job briefing

Where they Merge

- QA/QC and ISM Converge at the Facility-Level ISMS
- Quality in the nuclear business has its origins in facility safety : 10 CFR 50, Appendix B

QA/QC Assures Flow Down of Design Requirements

- Nuclear or High-Hazard Facilities: ISMS - QMS become one for safety-related SSC
 - Design
 - Acquisition
 - Receipt
 - Installation
 - Maintenance
 - Operation

Safety Basis Protection

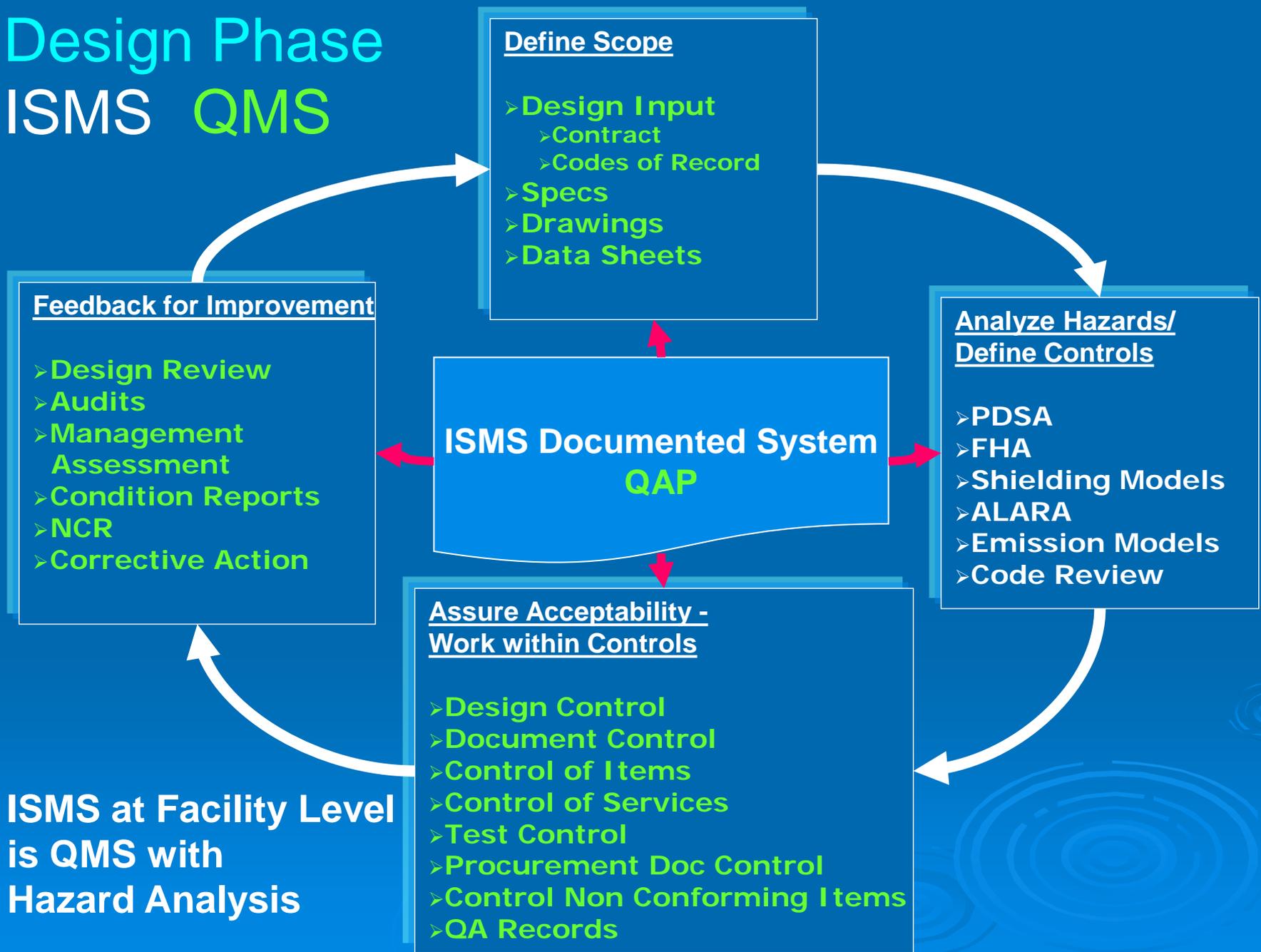
- PDSA and DAS define performance & functional requirements for credited SS/SC SSC
- The facility Design Basis translates performance & functional requirements into specific design requirements: Drawings, Data Sheets, Specifications, Receipt Inspection Criteria Packages, Commercial Grade Dedication Packages, Inspection Test Plans, etc.
- QA/QC's primary function for Nuclear Facility (particularly design build) is to assure **documented** fidelity between the design requirements and the received and installed SSCs

Latent versus Active Hazards

- QA/QC is of modest utility when considering active hazards, i.e., occupational safety and health
- QA/QC was conceived to protect the environment, the worker and the public when considering latent hazards
- *NQA-1 - Condition adverse to quality: “. . . A significant condition adverse to quality is one which, if uncorrected, could have a serious effect on safety or operability.”*

Design Phase

ISMS QMS



ISMS at Facility Level
is QMS with
Hazard Analysis

What Do We Integrate?

- A robust **QMS** will assure safety-related systems meet design requirements
- **Design Controls** assure SC/SS SSC functional and performance requirements flow down to the design requirements
- QMS fits under the ISMS:
 - QA/QC is a functional area no different from Nuclear Safety, Radiation Protection, Environmental Protection, Industrial Hygiene, etc. Each needs individual focus with integration to produce a safe product (e.g., waste treatment facility, power plant, processing facility).

It's The Management System . . .

- NUREG-1055, 1987 Report to Congress
 - Commercial nuclear quality failures in the 1970s and '80s resulted not from poor QMS
 - **Failures** resulted from broader **Management System weakness** touching all aspects of the organization
 - We need to focus on THE MANAGEMENT SYSTEM from a holistic perspective

Human and Process Elements

- Organizational performance is a function of **processes** and the **qualities of the personnel**
- I contend that no organization can conduct complex missions successfully w/o a Management System containing the basic elements of ISMS

Human Element

Guiding Principles (GP)... Approximately

1. Organizational priorities: Safety/Quality, Schedule, & Cost (**GP4**)
2. Authorities and Accountabilities (**GP1**)
3. Responsibilities and Functions (**GP2, CR1**)
4. Competencies & Qualifications (**GP3, CR2**)
5. Communication: Includes SCWE, HPI (The too often neglected “I” in ISMS)

DOE O 414.1C: CR = Criteria 1 – 10,

Process Elements

Core Functions (CF) + 2 Guiding Principles Approximately

1. Define scope and requirements: **CF1, GP5**
2. Analyze the risks (hazard if probability = 1): **CF2**
3. Tailor risk control strategies based on consequences or probabilities: **CF3, GP6, CR4, Graded Approach**
4. Verify that risk controls are in place: **CF4, GP6**
5. Authorize the activity within defined risk controls: **GP6**
6. Conduct activities based on controls and scope: **CF4, CR5, 6, 7**
7. Evaluate and measure performance: **CF5, CR3, 8, 9, & 10**
8. Improve based on performance analysis: **CF5, CR3, 8, 9, & 10**

It's Not Just About Safety

- **If an organization with a complex or hazardous mission is not following the management system elements for major aspects of their endeavor – not just safety – it's heading for performance problems if not failure**

Conclusions

- If the correct policies, plans and procedures are in place to support ISMS & QMS, then integration should be implicit and passive versus explicit and active.
- Integration needs to be explicit and active between organizations and disciplines responsible for the identification, design, acquisition, acceptance and installation of safety-related SSC